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TESTIMONY OF DR. DEBRA MATHEWS AT HEARING ENTITLED

**“Human Cloning and Embryonic Stem Cell Research After Seoul: Examining Exploitation, Fraud,
and Ethical Problems in the Research”**

**BEFORE THE SUBCOMMITTEE ON CRIMINAL JUSTICE, DRUG POLICY AND HUMAN
RESOURCES**

MARCH 7, 2006

Chairman and members of the Committee, thank you for this opportunity to share my thoughts. My name is Debra Mathews and I am the Assistant Director for Science Programs at the Phoebe R Berman Bioethics Institute at Johns Hopkins University. I am a human geneticist and also have a degree in bioethics. I am speaking to you today as a scientist and as an ethics and science policy scholar. I have spent the last decade doing scientific research and now spend my life thinking about the scientific community's interactions with and impact on the world outside the laboratory.

While the situation that occurred in and around the laboratory of Dr. Hwang Woo-suk is deeply lamentable, it is not representative of the field of stem cell research, nor a barrier to the progress of this research with ethical and scientific integrity. Scientists throughout the world are actively taking steps to ensure the integrity of their own work and the field more broadly.

No one can promise that stem cell research will produce cell-based cures for currently untreatable diseases; however, scientists who conduct this research do see promise in the research for advancing understanding of early human development and human disease and disability. While the lines approved for federal funding by President Bush are suitable for basic studies of, for example, embryonic stem cells themselves, the culture conditions necessary to keep cells healthy and genetically stable, and how to direct the differentiation of pluripotent stem cells into specialized cell types like neurons and islet cells, they are not suitable for many other areas of research. The approved lines were derived very early in the history of human embryonic stem cell science, for example, before optimal – mouse-free – cell culture conditions had been developed. Newly derived lines benefit from almost five years of scientific knowledge and technological advance, ensuring that they are more robust and stable than most approved lines, and uncontaminated by products from non-human animals. Newly derived lines – from IVF embryos in excess of clinical need and from somatic cell nuclear transfer (SCNT) – allow scientists to address a whole set of questions unanswerable through the use of the approved lines. For example, embryos created through IVF in the course of reproductive services, which contain disease-causing genetic mutations and will therefore never be used to create a baby, can be used to derive stem cells that allow scientists to study how the genetic mutation causes disease, providing vital basic information that may help in the development of treatments for that disease. SCNT facilitates the study of conditions for which genetic mutations are not known, or do not

apply, such as schizophrenia, amyotrophic lateral sclerosis (ALS), diabetes and stroke. In addition, SCNT opens the possibility in the (likely distant) future for disease treatments that use a patient's own cells to treat their condition, reducing the likelihood of immune rejection and the need for adjunct immunosuppressive therapy.

SCNT does raise the issue of egg donation for research purposes. This is a complicated and controversial topic, and one that scientists, ethicists and others are working to address. Many argue that egg donation for research purposes can be done ethically. The National Academy of Sciences issued guidelines in 2005 which address not only the oversight of stem cell research, but also provide guidance on egg donation. These guidelines have been broadly adopted by research institutions across the United States. The California Institute for Regenerative Medicine (CIRM) has recently announced their new interim guidelines, in which they go above and beyond the National Academy's guidelines in their attempt to protect from exploitation women who choose to donate eggs. In addition, CIRM has partnered with the Society for Gynecologic Investigation on a scientific conference in May examining the risks of egg donation. The message from the scientific community is very clear – they understand and are prepared to address the ethical issues raised by stem cell research, including egg donation for research purposes.

An issue that is not unique to SCNT or stem cell research broadly is that of fraud. Fraud occurs in all walks of life and in all fields of research. It is fortunately rare and the process of science, involving peer review and replication before findings are accepted, is well equipped to detect fraud when it does occur. However, fraud may not be detected until other scientists attempt to replicate experiments, or many, many scientists have had the opportunity to scrutinize the work. Peer review is equipped to detect bad science and bad fraud, but it is not set up to detect good fraud. If someone wants to intentionally deceive and is clever about it, it is very difficult to detect. While the papers from Dr. Hwang's lab were published, the fraud was quickly recognized by members of the scientific community and the scientific record corrected.

Again, scientists are just as concerned about fraud as non-scientists and they appreciate that in a controversial area like embryonic stem cell research, additional attention must be paid. Usually, the process of oversight associated with federal funding provides some protection against breaches of scientific and ethical integrity. As much embryonic stem cell research in the US does not receive federal funds, other oversight mechanisms must be relied upon, such as university internal review boards (IRBs) and embryonic stem cell research oversight committees (ESCROs), as recommended by the National Academy's guidelines. Recently, the National Academy of Sciences announced that they would set up a committee to provide an additional level of oversight of stem cell research. In addition, groups such as the International Society for Stem Cell Research has established a task force to develop international guidelines to govern stem cell research. Also recently, an international group of scientists, ethicists, journal editors and others issued a consensus statement offering principles by which international collaboration in stem cell research ought to proceed and through which we can foster the ethical and scientific integrity of stem cell science in a global context.

Scientists in the United States and around the world recognize both the promise and the controversy of stem cell research. There will always be bad actors, but they will be the exceptions. Scientists, in collaboration with their institutions, ethicists, journal editors, the public, and others must and are devising guidance and standards to minimize the risk that events such as those that unfolded in South Korea are repeated.